



# BOTTI & FERRARI

EUROPEAN PATENT ATTORNEYS\*  
BREVETTI & MARCHI

## Ufficio di Milano

Tel. +39 02 67 04 275

+39 02 67 03 243

Fax +39 02 67 03 250

✉ milano@botti-ferrari.com

<http://www.botti-ferrari.com>

MILANO (IT) - MUNICH (DE) - LUGANO (CH)

EPO

**EUROPEAN PATENT  
OFFICE**

D-80298 München  
GERMANY

Milano, May 29, 2008

Your ref.: **05711599.0-2123**

Our ref.: **CFS001WEP/RF/fa**

Re: European Patent Application No. **05711599.0**

in the name of: **University of Miami**

Dear Sirs,

With reference to the above identified patent application and to your Communication pursuant to Rule 70(2) EPC dated April 29, 2008, we hereby confirm the Applicant's interest in proceeding further with the examination phase.

Many thanks and best regards.

Yours Sincerely,  
The Representative

  
Rinaldo Ferreccio

Botti & Ferrari S.r.l.  
Via Locatelli, 5  
I-20124 Milano (Italy)

Cap. Soc. 90,000 euro  
C.F./P. IVA 1268239015  
R.E.A. MI 1577190

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**EURATTORNEYS**  
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## MILANO (Head Office)

Mario Botti \*  
Barbara Ferrari \*  
Torquato Vannini \*  
Rinaldo Ferreccio \*  
Marco Zardi \*  
M. Caterina Spera  
Umberto Zambardino \*  
Roberto De Nova \*  
Sabrina Piumagalli  
Antonio Zenti  
Alberto Zuccollo

## BOLOGNA

M. Caterina Spera  
Pietro Paglia \*  
Tamara Casci  
P.za dei Martiri 1943-1945,  
I-40121 Bologna (Italy)  
Tel. +39 051 4075 744  
Fax +39 051 4075 745  
✉ [bologna@botti-ferrari.com](mailto:bologna@botti-ferrari.com)

## VERONA

Marta Manfrin \*  
Monica Bortolan  
Via Farinati d. Uberti, 10,  
I-37126 Verona (Italy)  
Tel. +39 045 83 52 083  
Fax +39 045 83 05 434  
✉ [verona@botti-ferrari.com](mailto:verona@botti-ferrari.com)

## Network Members

Huber & Schuessler  
Truderinger Str. 246  
D-81825 MUNICH  
(Germany)  
✉ [info@patservice.de](mailto:info@patservice.de)

M. Zardi & Co. S.A.  
Via Pioda, 6  
CH-6900 LUGANO  
(Switzerland)  
✉ [info@zardi.ch](mailto:info@zardi.ch)



European Patent Office  
80298 MUNICH  
GERMANY  
Tel. +49 (0)89 2399 - 0  
Fax +49 (0)89 2399 - 4465



Ferreccio, Rinaldo  
c/o Botti & Ferrari S.r.l.  
Via Locatelli 5  
20124 Milano  
ITALIE

For any questions about  
this communication:  
Tel.: +31 (0)70 340 45 00

Date
29.04.08

Reference AKR062WEP	Application No./Patent No. 05711599.0 - 2123 PCT/US2005001581
Applicant/Proprietor University of Miami	

**Proceeding further with the European patent application pursuant to Rule 70(2) EPC**

A supplementary European search report has been drawn up concerning the above European patent application (publication number 1718283).

Since a request for examination has been filed (R. 70(1) EPC) and the examination fee has been paid (Art. 94(1) EPC) prior to the transmission of the supplementary European search report, you are hereby invited to indicate within

**two months**

of notification of this invitation whether you desire to proceed further with the European patent application.

If you do not indicate in due time that you desire to proceed further with the European patent application, it will be deemed to be withdrawn (R. 70(3) EPC).

If you wish you may comment on the supplementary European search report and amend, where appropriate, the description, claims and drawings (R. 70(2) EPC).

**Receiving Section**





European Patent Office  
80298 MUNICH  
GERMANY  
Tel. +49 (0)89 2399 - 0  
Fax +49 (0)89 2399 - 4465



Ferreccio, Rinaldo  
c/o Botti & Ferrari S.r.l.  
Via Locatelli 5  
20124 Milano  
ITALIE

For any questions about  
this communication:  
Tel.: +31 (0)70 340 45 00

Date
10.04.08

Reference AKR062WEP	Application No / Patent No. 05711599.0 - 2123 PCT/US2005001581
Applicant/Proprietor University of Miami	

#### Communication

The European Patent Office herewith transmits as an enclosure the supplementary European search report under Article 153(7) EPC for the above-mentioned European patent application.

If applicable, copies of the documents cited in the European search report are attached.

- ☐ Additional set(s) of copies of the documents cited in the European search report is (are) enclosed as well.

#### Refund of the search fee

If applicable under Article 9 Rules relating to fees, a separate communication from the Receiving Section on the refund of the search fee will be sent later.





European Patent  
Office

**SUPPLEMENTARY  
EUROPEAN SEARCH REPORT**

Application Number  
**EP 05 71 1599**

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	US 2002/156302 A1 (WEST DANIEL DAVID [US]) 24 October 2002 (2002-10-24) * paragraphs [0009], [0039]; claim 9 * -----	1-30	INV. A61K31/351 A61K47/24 A61P35/00
X	DATABASE MEDLINE [Online] US NATIONAL LIBRARY OF MEDICINE (NLM), BETHESDA, MD, US; March 1983 (1983-03), KOKAWA T ET AL: "[Coenzyme Q10 in cancer chemotherapy--experimental studies on augmentation of the effects of masked compounds, especially in the combined chemotherapy with immunopotentiators]" XP002473825 Database accession no. NLM6881995 * abstract * & GAN TO KAGAKU RYOH0. CANCER & CHEMOTHERAPY MAR 1983, vol. 10, no. 3, March 1983 (1983-03), pages 768-774, ISSN: 0385-0684 -----	16-18	
X	US 2002/039595 A1 (KELLER BRIAN C [US]) 4 April 2002 (2002-04-04) * example 2 * -----	2,26-30	TECHNICAL FIELDS SEARCHED (IPC) A61K A61P
The supplementary search report has been based on the last set of claims valid and available at the start of the search.			
Place of search <b>Munich</b>		Date of completion of the search <b>25 March 2008</b>	Examiner <b>Zimmer, Barbara</b>
<b>CATEGORY OF CITED DOCUMENTS</b> X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons ----- & : member of the same patent family, corresponding document			

**ANNEX TO THE EUROPEAN SEARCH REPORT  
ON EUROPEAN PATENT APPLICATION NO.**

EP 05 71 1599

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on  
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

25-03-2008

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2002156302 A1	24-10-2002	US 2004151711 A1	05-08-2004
US 2002039595 A1	04-04-2002	NONE	



# BOTTI & FERRARI

EUROPEAN PATENT ATTORNEYS\*  
BREVETTI & MARCHI

## Ufficio di Milano

Tel. +39 02 67 04 275  
+39 02 67 03 243  
Fax +39 02 67 03 250  
✉ milano@botti-ferrari.com

<http://www.botti-ferrari.com>

MILANO (IT) - MUNICH (DE) - LUGANO (CH)

Botti & Ferrari S.r.l.  
Via Locatelli, 5  
I-20124 Milano (Italy)

Cap. Soc. 90,000 euro  
C.F./P. IVA 12682390153  
R.E.A. MI 1577190

member of  
**EURATTORNEYS**  
www.eurattorneys.com

**EUROPEAN PATENT OFFICE**  
D-80298 MUNICH EPO - Munich  
GERMANY 54

20. Nov. 2007

Milano, November 14, 2007

Your Ref.: **05711599.0 - 2123**

Our ref.: **AKR062WEP/RF/mf**

Re: **European Patent Application No. 05711599.0 filed on 21/01/2005 and concerning: "Topical co-enzyme Q10 formulations and methods of use."**

in the name of: **University of Miami**

Dear Sirs,

with reference to the above-identified patent application, we would be glad if you could let us know, at your earliest convenience, when we can expect to receive the Supplementary Search Report..

Many thanks and best regards.

Yours Faithfully,  
The Representative

  
Rinaldo Ferreccio

### MILANO (Head Office)

Mario Botti \*  
Barbara Ferrari \*  
Torquato Vannini \*  
Rinaldo Ferreccio \*  
Marco Zardi \*  
M. Caterina Spera  
Umberto Zambardino \*  
Roberto De Nova \*  
Sabrina Fumagalli  
Antonio Zenti  
Alberto Zuccollo

### BOLOGNA

M. Caterina Spera  
Pietro Paglia  
Tamara Casci  
P.zza dei Martiri 1943-1945, 5  
I-40121 Bologna (Italy)  
Tel. +39 051 4075 744  
Fax +39 051 4075 745  
✉ bologna@botti-ferrari.com

### VERONA

Marta Manfrin \*  
Monica Bortolan  
Via Farinati d. Uberti, 10  
I-37126 Verona (Italy)  
Tel. +39 045 83 52 083  
Fax +39 045 83 05 434  
✉ verona@botti-ferrari.com

### Network Members

**Huber & Schuessler**  
Truderinger Str. 246  
D-81825 MUNICH  
(Germany)  
✉ info@patservice.de

**M. Zardi & Co. S.A.**  
Via Pioda, 6  
CH-6900 LUGANO  
(Switzerland)  
✉ info@zardi.ch



# BOTTI & FERRARI

EUROPEAN PATENT ATTORNEYS\*  
BREVETTI & MARCHI

## Ufficio di Milano

Tel. +39 02 67 04 275  
+39 02 67 03 243  
Fax +39 02 67 03 250  
✉ milano@botti-ferrari.com

<http://www.botti-ferrari.com>

MILANO (IT) - MUNICH (DE) - LUGANO (CH)

Botti & Ferrari S.r.l.  
Via Locatelli, 5  
I-20124 Milano (Italy)

Cap. Soc. 90,000 euro  
C.F./P. IVA 12682390153  
R.E.A. MI 1577190

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**EPO**  
**EUROPEAN PATENT OFFICE**  
**D-80298 MÜNCHEN**  
**Germany**

Milano, June 26, 2007

EPO - Munich  
3

06. Juli 2007

Your Ref.: **05711599.0-2107**  
Our ref.: **AKR062WEP/RF/fa**

Re: **European Patent Application No. 05711599.0** filed on  
21/01/05 concerning: "Topical co-enzyme Q10 formulations  
and methods of use."

in the name of: **University of Miami**

Dear Sirs,

we hereby confirm that the address indicated in your Notification pursuant  
to Part A-III, 5.3 of the Guidelines for Examination in the EPO issued on  
November 9, 2006 with reference to the above identified patent application,  
i.e.

**3871 Boca Pointe Dr.**  
**Sarasota, FL 34238**  
**U.S.A.**

is the correct, current domicile of Ms. RUSSEL, Kathryn.

Many thanks and best regards.

Yours Sincerely,  
The Representative

  
Rinaldo Ferreccio

## MILANO (Head Office)

Mario Botti \*  
Barbara Ferrari \*  
Torquato Vannini \*  
Rinaldo Ferreccio \*  
Marco Zardi \*  
M. Caterina Spera  
Umberto Zambardino \*  
Roberto De Nova \*  
Sabrina Fumagalli  
Antonio Zenti  
Alberto Zuccollo

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M. Caterina Spera  
Pietro Paglia  
Tamara Casci  
P.za dei Martiri 1943-1945, 5  
I-40121 Bologna (Italy)  
Tel. +39 051 4075 744  
Fax +39 051 4075 745  
✉ bologna@botti-ferrari.com

## VERONA

Marta Manfrin \*  
Monica Bortolan  
Via Farinati d. Uberti, 10  
I-37126 Verona (Italy)  
Tel. +39 045 83 52 083  
Fax +39 045 83 05 434  
✉ verona@botti-ferrari.com

## Network Members

**Huber & Schuessler**  
Truderinger Str. 246  
D-81825 MUNICH  
(Germany)  
✉ info@patservice.de

**M. Zardi & Co. S.A.**  
Via Pioda, 6  
CH-6900 LUGANO  
(Switzerland)  
✉ info@zardi.ch



European Patent Office  
80298 MUNICH  
GERMANY  
Tel.: +49 89 2399 - 0  
Fax: +49 89 2399 - 4465

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Ferreccio, Rinaldo  
c/o Botti & Ferrari S.r.l.  
Via Locatelli 5  
20124 Milano  
ITALIE



EPO Customer Services

Tel.: +31 (0)70 340 45 00

Date  
30.03.07

Reference AKR062WEP	Application No./Patent No. 05711599.0 - 2123
Applicant/Proprietor University of Miami	

### Communication

concerning the registration of amendments relating to

- ☐ a transfer (Rules 20 and 61 EPC)
- ☒ entries pertaining to the applicant/the proprietor (Rule 92(1)(f) EPC)

As requested, the entries pertaining to the applicant of the above-mentioned European patent application / to the proprietor of the above-mentioned European patent have been amended to the following:

AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU MC NL  
PL PT RO SE SI SK TR  
University of Miami  
1475 NW 12th Avenue, Suite 2012  
Miami, FL 33136/US

The registration of the changes has taken effect on 22.02.07.

In the case of a published application/a patent, the change will be recorded in the Register of European Patents and published in the European Patent Bulletin (Section I.12/II.12).

Your attention is drawn to the fact that, in the case of the registration of a transfer, any automatic debit order only ceases to be effective from the date of its express revocation (cf. point 14(c) of the Arrangements for the automatic debiting procedure, Supplement to OJ EPO 2/2002).

**Transfer Service**  
Tel.: +49 (0)89 2399 2780







# BOTTI & FERRARI

EUROPEAN PATENT ATTORNEYS\*  
BREVETTI & MARCHI

info@Botti-Ferrari.com  
http://www.Botti-Ferrari.com

EPO - Munich  
40

22 Feb. 2007

Ufficio di Milano

Tel. +39 02 67 04 275

+39 02 67 03 243

Fax +39 02 67 03 250

MILANO (IT) - MUNICH (DE) - LUGANO (CH) - MADRID (ES)

Botti & Ferrari S.r.l.  
Via Locatelli, 5  
I-20124 Milano (Italy)

Cap. Soc. 90,000 euro  
C.F./P. IVA 12682390153  
R.E.A. MI 1577190

member of  
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EUROPEAN ASSOCIATION OF PATENT ATTORNEYS  
www.eurattorneys.com

**EPO**

**EUROPEAN PATENT OFFICE**

**D-80298 MÜNCHEN**

**Germany**

Milan, February 13, 2007

Your Ref.: **05711599.0-2107**

Our ref.: **AKR062WEP/RF/fa**

Re: European Patent Application No. **05711599.0** filed on  
21/01/05 concerning: "Topical co-enzyme Q10 formulations  
and methods of use."

in the name of: **University of Miami**

Dear Sirs,

making reference to the above-identified application, we inform you that  
the Applicant has moved their legal seat to:

**1475 NW 12<sup>th</sup> Avenue, Suite 2012**  
**Miami, FL 33136**  
**U.S.A.**

Please, amend your files in this respect.

Many thanks and best regards.

Yours Sincerely,  
The Representative

Rinaldo Ferreccio

## MILANO

Mario Botti \*  
Barbara Ferrari \*  
Torquato Vannini \*  
Rinaldo Ferreccio \*  
Marco Zardi \*  
M. Caterina Spera  
Umberto Zambardino \*  
Roberto De Nova \*  
Loredana Portoghese  
Sabrina Fumagalli  
Antonio Zenti  
Stefano Sinigaglia  
Tamara Casci

## MODENA

Alberto Gasparini  
M. Caterina Spera  
Palazzo Salimbeni  
C.so Cavour, 36  
I-41100 Modena (Italy)  
Tel. +39 059 23 45 06  
Fax +39 059 43 99 893  
✉ info@finderoute.it

## VERONA

Marta Manfrin \*  
Via Farinati d. Uberti, 10  
I-37126 Verona (Italy)  
Tel. +39 045 83 52 083  
Fax +39 045 83 05 434

## VICENZA

Monica Bortolan  
Contrà Apolloni, 27  
I-36100 Vicenza (Italy)  
Tel. +39 0444 32 01 32  
Fax +39 0444 23 43 21

## Network Members

**Huber & Schuessler**  
Truderinger Str. 246  
D-81825 MUNICH  
(Germany)  
✉ munich@huber-  
schuessler.info

**M. Zardi & Co. S.A.**  
Via Piada, 6  
CH-6900 LUGANO  
(Switzerland)  
✉ info@zardi.ch

**ABG PATENTES**  
C/Orense 68, 7<sup>a</sup> Floor  
E-28020 MADRID  
(Spain)  
✉ informacion@abg  
patentes.com

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 16 JAN 2007

WIPO

PCT

Applicant's or agent's file reference <b>7230-21WO</b>	<b>FOR FURTHER ACTION</b>	See Form PCT/IPEA/416
International application No. <b>PCT/US05/01581</b>	International filing date (day/month/year) <b>21 January 2005 (21.01.2005)</b>	Priority date (day/month/year) <b>22 January 2004 (22.01.2004)</b>
International Patent Classification (IPC) or national classification and IPC <b>IPC: A61K 31/35 (2006.01)</b> <b>USPC: 514/460</b>		
Applicant <b>UNIVERSITY OF MIAMI</b>		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p style="margin-left: 20px;">a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>4</u> sheets, as follows:</p> <div style="margin-left: 40px;"> <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).  <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.         </div> <p style="margin-left: 20px;">b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <div style="margin-left: 20px;"> <input checked="" type="checkbox"/> Box No. I      Basis of the report  <input type="checkbox"/> Box No. II      Priority  <input type="checkbox"/> Box No. III      Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  <input type="checkbox"/> Box No. IV      Lack of unity of invention  <input checked="" type="checkbox"/> Box No. V      Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement  <input type="checkbox"/> Box No. VI      Certain documents cited  <input type="checkbox"/> Box No. VII      Certain defects in the international application  <input type="checkbox"/> Box No. VIII      Certain observations on the international application         </div>		
Date of submission of the demand <b>22 September 2005 (22.09.2005)</b>	Date of completion of this report <b>18 December 2006 (18.12.2006)</b>	
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer <b>Zohreh Vakili</b> <i>J. Roberts for</i> Telephone No. 571-272-3099	

Form PCT/IPEA/409 (cover sheet)(April 2005)

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US05/01581

## Box No. I Basis of the report

1. With regard to the language, this report is based on:

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4(a))
  - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☐ the international application as originally filed/furnished
- ☒ the description:  
pages 1-11, 13-47 and 50 as originally filed/furnished  
pages\* NONE received by this Authority on \_\_\_\_\_  
pages\* 13, 48 and 49 received by this Authority on 13 December 2005 (13.12.2005)
- ☒ the claims:  
pages 51-54 as originally filed/furnished  
pages\* NONE as amended (together with any statement) under Article 19  
pages\* NONE received by this Authority on \_\_\_\_\_  
pages\* NONE received by this Authority on \_\_\_\_\_
- ☒ the drawings:  
pages 1-13 and 15-30 as originally filed/furnished  
pages\* NONE received by this Authority on \_\_\_\_\_  
pages\* 14 received by this Authority on 13 December 2005 (13.12.2005)
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs. \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

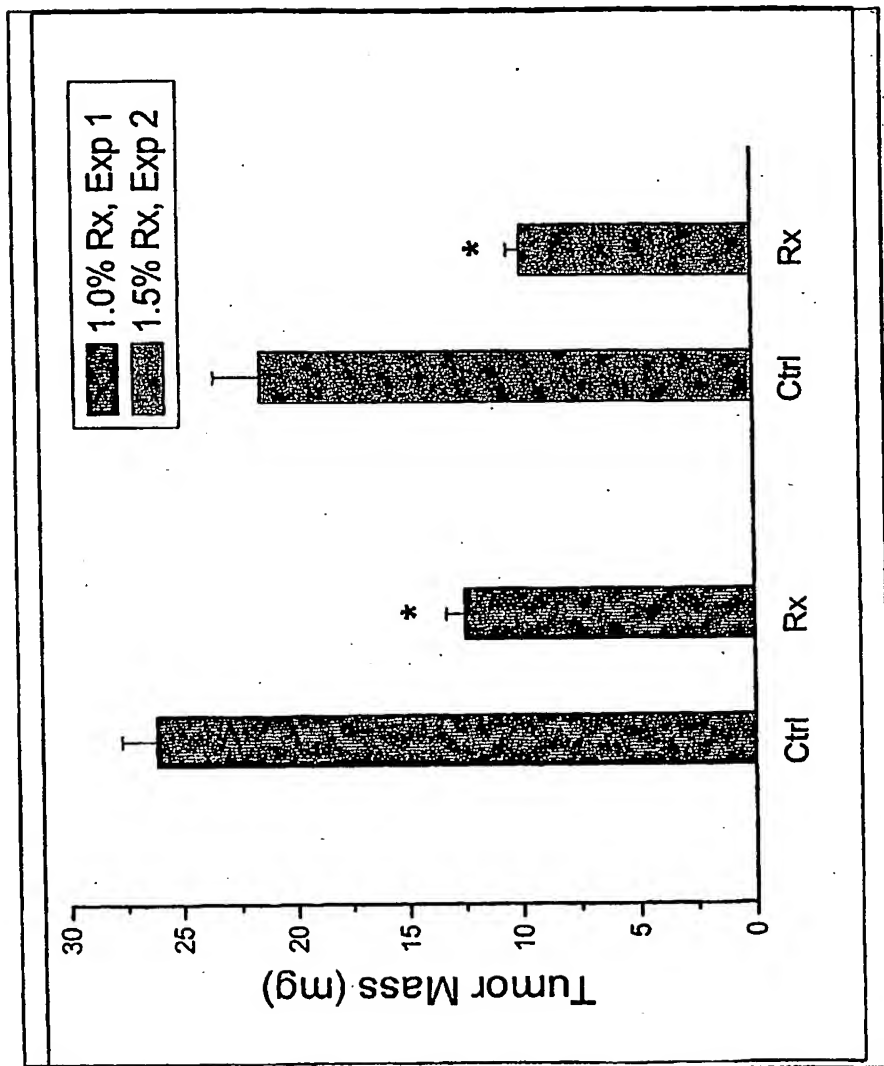
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs. \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

14/30

# Effect of Topical CoQ10 on SKMEL28 Tumor Mass in Nude Mice



Average tumor mass for the control vs. treatment group decreased by 52.3% and 54.0%, respectively FIG. 14

AMENDED SHEET

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
4 August 2005 (04.08.2005)

PCT

(10) International Publication Number  
**WO 2005/069916 A3**

(51) International Patent Classification:  
A61K 31/35 (2006.01)

(21) International Application Number:  
PCT/US2005/001581

(22) International Filing Date: 21 January 2005 (21.01.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
60/538,319 22 January 2004 (22.01.2004) US

(71) Applicant (for all designated States except US): UNIVERSITY OF MIAMI [US/US]; 1400 NW 10th Avenue, Suite 906, Miami, FL 33136 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): HSIA, Sung, Lan [US/US]; 13701 SW 72nd Avenue, Miami, FL 33158 (US). NARAIN, Niven, Rajin [GY/US]; 850 N. Miami Avenue, Apt. 1607W, Miami, FL 33136 (US). LI, Jie [CN/US]; 69-04 N. Kendall Dr. #F307, Miami, FL 33156 (US). RUSSELL, Kathryn, J. [US/US]; 3871 Boca Pointe Dr., Sarasota, FL 34238 (US). WOAN, Karrune, V. [US/US]; 1516 Red Pine Trail, Wellington, FL 33414 (US). PERSAUD, Indushekhar [US/US]; 168-30 SW 240th Street, Homestead, FL 33031 (US).

(74) Agent: NELSON, Gregory, A.; Akerman Senterfitt, Customer No. 30448, P.O. Box 3188, West Palm Beach, FL 33402-3188 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

(88) Date of publication of the international search report:  
19 October 2006

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 2005/069916 A3

(54) Title: TOPICAL CO-ENZYME Q10 FORMULATIONS AND METHODS OF USE

(57) Abstract: Topical formulations of CoQ10 reduce the rate of tumor growth in an animal subject. In the experiments described herein, CoQ10 was shown to increase the rate of apoptosis in a culture of skin cancer cells but not normal cells. Moreover, treatment of tumor-bearing animals with a topical formulation of CoQ10 was shown to dramatically reduce the rate of tumor growth in the animals.

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US05/01581

## A. CLASSIFICATION OF SUBJECT MATTER

IPC: A61K 31/35( 2006.01)

USPC: 514/460

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
U.S. : 514/460

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
Please See Continuation Sheet

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 6,582,723 B (GORSEK) 24 June 2003 (24.06.2003), see the entire document.	1, 6-10, 15-32 ----- 12-14

<input type="checkbox"/> Further documents are listed in the continuation of Box C.	<input type="checkbox"/> See patent family annex.
<p>* Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p>	<p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&amp;" document member of the same patent family</p>

Date of the actual completion of the international search 06 August 2006 (06.08.2006)	Date of mailing of the international search report 31 AUG 2006
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Jean C. Witz Telephone No. (571) 272-0700

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US05/01581

Continuation of B. FIELDS SEARCHED Item 3:  
USPAT, USPGPUB, JPO, EPO, DERWENT, BIOSIS, MEDLINE, INPADOC, CAPLUS:  
search terms: coenzyme q10 and (cancer or tumor)



P.B.5818 - Patentlaan 2  
2280 HV Rijswijk (ZH)  
☎ (070) 3 40 20 40  
FAX (070) 3 40 30 16

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Generaldirektion 1

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Direction générale 1

Ferreccio, Rinaldo  
c/o Botti & Ferrari S.r.l.  
Via Locatelli 5  
20124 Milano  
ITALIE



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Tel.: +31 (0)70 340 45 00

Date

11.10.06

Reference  
AKR062WEP

Application No./Patent No.  
05711599.0 - 2107 PCT/US2005001581

Applicant/Proprietor  
University of Miami

#### Notification of European publication number and information on the application of Article 67(3) EPC

The provisional protection under Article 67(1) and (2) EPC in the individual contracting states becomes effective only when the conditions referred to in Article 67(3) EPC have been fulfilled (for further details, see information brochure of the European Patent Office "National Law relating to the EPC" and additional information in the Official Journal of the European Patent Office).

A request has been made for extension of the patent to: AL BA HR LV MK YU  
See Official Journal 1-2/1994 for further information on provisional protection.

Pursuant to Article 158(1) EPC the publication under Article 21 PCT of an international application for which the European Patent Office is a designated Office takes the place of the publication of a European patent application.

The bibliographic data of the above-mentioned Euro-PCT application will be published on 08.11.06 in Section I.1 of the European Patent Bulletin. The European publication number is 1718283.

In all future communications to the European Patent Office, please quote the application number plus Directorate number.

Receiving Section







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Ferreccio, Rinaldo  
c/o Botti & Ferrari S.r.l.  
Via Locatelli 5  
20124 Milano  
ITALIE



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Tel.: +31 (0)70 340 45 00

Date  
20.09.06

Reference AKR062WEP	Application No./Patent No. 05711599.0-2107-US2005001581
Applicant/Proprietor University of Miami	

### Refund of fees

The following fees were paid in respect of the application 05711599.0:

Fee	Code	Voucher No	Date	Currency	Amount
Search fee	002	00530966	11.08.06	EUR	720,00

### REFUND ORDER

- According to Art. 157(3)b) EPC a 20 % reduction of the search fee is given (see also OJ EPO 1994, 691). The overpaid amount will be refunded.
- The refund will be done by:  
CREDITING THE DEPOSIT ACCOUNT 28070103.

Amount refundable:	Code	Currency	Amount	Voucher No
	002	EUR	144,00	00579294
<b>Total:</b>		<b>EUR</b>	<b>144,00</b>	

The Authorising Officer  
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Generaldirektion 1

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RUSSELL, Kathryn, J.  
3871 Boca Pointe Dr.  
Sarasota, FL 34238  
ETATS-UNIS D'AMERIQUE



**EPO Customer Services**

Tel.: +31 (0)70 340 45 00

Date  
08.09.06

Reference	Application No./Patent No. 05711599.0-2107-US2005001581
Applicant/Proprietor University of Miami	

**Notification of the data mentioned in Article 128(5) EPC pursuant to Rule 17(3) EPC**

In the above-identified patent application you are designated as inventor/co-inventor.  
Pursuant to Rule 17(3) EPC the data as mentioned in Article 128(5) EPC are notified herewith:

DATE OF FILING : 21.01.05  
PRIORITY : US/22.01.04/ USP 538319  
TITLE : TOPICAL CO-ENZYME Q10 FORMULATIONS AND METHODS OF USE  
DESIGNATED STATES : AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU MC NL PL PT RO SE SI SK TR

**RECEIVING SECTION**



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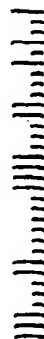
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E. Verduist

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Generaldirektion 1

Directorate General 1

Direction générale 1

Ferreccio, Rinaldo  
c/o Botti & Ferrari S.r.l.  
Via Locatelli 5  
20124 Milano  
ITALIE



EPO Customer Services

Tel.: +31 (0)70 340 45 00

Date

12-09-2006

Reference AKR062WEP	Application No./Patent No. 05711599.0 - 2107 PCT/US2005001581
Applicant/Proprietor University of Miami	

#### Communication pursuant to Rules 109 and 110 EPC

##### (1) Amendment of application documents, especially the claims (R. 109 EPC)

The above mentioned international (Euro-PCT) application has entered the European phase, or can do so, once the necessary conditions are fulfilled.

Under Articles 28, 41 PCT, Rules 52, 78 PCT and Rule 86(2) to (4) EPC, the applicant may amend the application documents after receiving the international search report.

**Whether or not he has already done so, he now has a further opportunity to file amended claims or other application documents within a non-extendable time limit of one month after notification of the present communication (R. 109 EPC).**

The claims applicable on expiry of the above time limit, i.e. those filed on entry into the European phase or in response to the present communication, will form the basis for the calculation of any claims fee to be paid (see page 2) and for any supplementary search to be carried out under Article 157(2) EPC (R. 109 EPC).

--2/

**(2) Claims fees under Rule 110 EPC**

If the application documents on which the European grant procedure is to be based comprise more than ten claims, a claims fee shall be payable for the eleventh and each subsequent claim within the period provided for in Rule 107(1) EPC.

- ☒ Based on the application documents currently on file, all necessary claims fees have already been paid (or the documents do not comprise more than 10 claims).
- ☐ All necessary fees will be/have been debited automatically according to the automatic debit order.
- ☐ The claims fee due for the claims ..... to ..... were not paid within the above-mentioned period.

Any non-paid claims fee, either based on the current set of claims or on any amended claims to be filed pursuant to Rule 109 EPC (see page 1), may still be validly paid within a non-extendable period of grace of **one month** after notification of this communication.

If a payment is made for only some of the claims, it must be indicated for which claims it is intended. If a claims fee is not paid in due time, the claim concerned is deemed to be abandoned (R. 110(4) EPC).

If claims fees have already been paid, but on expiry of the above-mentioned time limit there is a new set of claims containing fewer fee-incurring claims than previously, the claims fees in excess of those due under Rule 110(2), 2nd sentence, EPC will be refunded (R. 110(3) EPC).

You are reminded that any supplementary search under Article 157(2) EPC will relate only to the last set of claims applicable on expiry of the above time limit AND will be confined to those fee-incurring claims for which fees have been paid in due time.

**The fee for the eleventh and each subsequent claim is EUR 45,00.**

Receiving Section



EPO - Munich  
59**Eintritt in die  
europäische Phase  
(EPA als Bestimmungsamt  
oder ausgewähltes Amt)****Entry into the  
European phase**  
1. Aug. 2006  
**(EPO as designated or  
elected Office)****Entrée dans la  
phase européenne  
(l'OEB agissant en qualité  
d'office désigné ou élu)**

Europäische Anmeldenummer oder, falls nicht bekannt, PCT-Aktenzeichen oder PCT-Veröffentlichungsnummer	European application number, or, if not known, PCT application or publication number  05711599.0/PCT/US05/01581	Numéro de dépôt de la demande de brevet européen ou, à défaut, numéro de dépôt PCT ou de publication PCT
Zeichen des Anmelders oder Vertreters (max. 15 Positionen)	Applicant's or representative's reference (max. 15 spaces)  AKR06ZWEP	Référence du demandeur ou du mandataire (15 caractères ou espaces au maximum)
<input checked="" type="checkbox"/> <b>1. Anmelder</b> Die Angaben über den (die) Anmelder sind in der internationalen Veröffentlichung enthalten oder vom Internationalen Büro nach der internationalen Veröffentlichung vermerkt worden.  <input type="checkbox"/> Änderungen, die das Internationale Büro noch nicht vermerkt hat, sind auf einem Zusatzblatt angegeben.  <b>Zustellanschrift</b> (siehe-Merkblatt II, 1)	<b>1. Applicant</b> Indications concerning the applicant(s) are contained in the international publication or recorded by the International Bureau after the international publication.  Changes which have not yet been recorded by the International Bureau are set out on an additional sheet.  <b>Address for correspondence</b> (see Notes II, 1)	<b>1. Demandeur</b> Les indications concernant le(s) demandeur(s) figurent dans la publication internationale ou ont été enregistrées par le Bureau international après la publication internationale.  Les changements qui n'ont pas encore été enregistrés par le Bureau international sont indiqués sur une feuille additionnelle.  <b>Adresse pour la correspondance</b> (voir notice II, 1)
<b>2. Vertreter</b>  <b>Name</b> (Nur einen Vertreter angeben, der in das europäische Patentregister eingetragen und an den zugestellt wird)  <b>Geschäftsanschrift</b>  <b>Telefon</b>  <b>Telefax</b> <b>Telex</b>  <input type="checkbox"/> Weitere(r) Vertreter auf Zusatzblatt	<b>2. Representative</b>  <b>Name</b> (Name only one representative who will be listed in the Register of European Patents and to whom notification will be made) FERRECCIO Rinaldo  <b>Address of place of business</b> BOTI & FERRARI S.r.l. Via Locatelli, 5 I-20124 Milano - Italy  <b>Telephone</b> +39 02 6704275  <b>Fax</b> <b>Telex</b> +39 02 6703250  Additional representative(s) on additional sheet	<b>2. Mandataire</b>  <b>Nom</b> (N'indiquer qu'un seul mandataire, qui sera inscrit au Registre européen des brevets et auquel signification sera faite)  <b>Adresse professionnelle</b>  <b>Téléphone</b>  <b>Téléfax</b> <b>Télex</b>  Autre(s) mandataire(s) sur une feuille additionnelle
<b>3. Vollmacht</b>  <input type="checkbox"/> Einzelvollmacht ist beigelegt.  <input type="checkbox"/> Allgemeine Vollmacht ist registriert unter Nummer:  <input type="checkbox"/> Allgemeine Vollmacht ist eingereicht, aber noch nicht registriert.  <input type="checkbox"/> Die beim EPA als PCT-Anmeldeamt eingereichte Vollmacht schließt ausdrücklich die europäische Phase ein.	<b>3. Authorisation</b>  Individual authorisation is attached.  General authorisation has been registered under No:  A general authorisation has been filed, but not yet registered.  The authorisation filed with the EPO as PCT receiving Office expressly includes the European phase.	<b>3. Pouvoir</b>  Un pouvoir spécial est joint.  Un pouvoir général a été enregistré sous le n°:  Un pouvoir général a été déposé, mais n'est pas encore enregistré.  Le pouvoir général déposé à l'OEB agissant en qualité d'office récepteur au titre du PCT s'applique expressément à la phase européenne.

Zur Kasse € 4750,-/A1

<p><input checked="" type="checkbox"/> <b>4. Prüfungsantrag</b> Hiermit wird die Prüfung der Anmeldung gemäß Art. 94 EPU beantragt. Die Prüfungsgebühr wird (wurde) entrichtet.</p> <p>Prüfungsantrag in einer zugelassenen Nichtamtssprache (siehe Merkblatt III, 5.2) :</p>	<p><b>4. Request for examination</b> Examination of the application under Art. 94 EPC is hereby requested. The examination fee is being (has been, will be) paid.</p> <p>Request for examination in an admissible non-EPO language (see Notes III, 5.2) :</p>	<p><b>4. Requête en examen</b> Il est demandé que soit examinée la demande de brevet conformément à l'art. 94 CBE. Il est (a été, sera) procédé au paiement de la taxe d'examen.</p> <p>Requête en examen dans une langue non officielle autorisée (voir notice III, 5.2) :</p>
<p><input type="checkbox"/> <b>5. Abschriften</b> Zusätzliche Abschrift(en) der im ergänzenden europäischen Recherchenbericht angeführten Schriftstücke wird (werden) beantragt.</p> <p>Anzahl der <b>zusätzlichen</b> Sätze von Abschriften</p>	<p><b>5. Copies</b> Additional copy (copies) of the documents cited in the supplementary European search report is (are) requested.</p> <p>Number of <b>additional</b> sets of copies</p>	<p><b>5. Copies</b> Prière de fournir une ou plusieurs copies supplémentaires des documents cités dans le rapport complémentaire de recherche européenne.</p> <p>Nombre de jeux <b>supplémentaires</b> de copies</p>
<p><b>6. Für das Verfahren vor dem EPA bestimmte Unterlagen</b></p> <p><b>6.1</b> Dem Verfahren vor dem EPA als <b>Bestimmungsamt (PCT I)</b> sind folgende Unterlagen zugrunde zu legen:</p> <p><input checked="" type="checkbox"/> die vom Internationalen Büro veröffentlichten <b>Anmeldungsunterlagen</b> (mit allen Ansprüchen, Beschreibung und Zeichnungen), gegebenenfalls mit den geänderten Ansprüchen nach Art. 19 PCT</p> <p><input checked="" type="checkbox"/> soweit sie nicht ersetzt werden durch die beigefügten <b>Änderungen</b>.</p> <p><i>Falls nötig, sind Klarstellungen auf einem Zusatzblatt einzureichen!</i></p> <p><b>6.2</b> Dem Verfahren vor dem EPA als <b>ausgewähltem Amt (PCT II)</b> sind folgende Unterlagen zugrunde zu legen:</p> <p><input checked="" type="checkbox"/> die dem Internationalen vorläufigen Prüfungsbericht zugrunde gelegten <b>Unterlagen</b>, einschließlich seiner eventuellen <b>Anlagen</b> (Solche Anlagen müssen immer beigefügt werden)</p> <p><input type="checkbox"/> soweit sie nicht ersetzt werden durch die beigefügten <b>Änderungen</b>.</p> <p><i>Falls nötig, sind Klarstellungen auf einem Zusatzblatt einzureichen!</i></p> <p><input checked="" type="checkbox"/> Sind dem EPA als mit der internationalen vorläufigen Prüfung beauftragten Behörde <b>Versuchsberichte</b> zugegangen, dürfen diese dem Verfahren vor dem EPA zugrunde gelegt werden.</p>	<p><b>6. Documents intended for proceedings before the EPO</b></p> <p><b>6.1</b> Proceedings before the EPO as <b>designated Office (PCT I)</b> are to be based on the following documents:</p> <p>the <b>application documents published</b> by the International Bureau (with <b>all</b> claims, description and drawings), where applicable with amended claims under Art. 19 PCT</p> <p>unless replaced by the <b>amendments</b> enclosed.</p> <p><i>Where necessary, clarifications must be submitted on a separate sheet!</i></p> <p><b>6.2</b> Proceedings before the EPO as <b>elected Office (PCT II)</b> are to be based on the following documents:</p> <p>the <b>documents on which the international preliminary examination report is based</b>, including its possible <b>annexes</b> (Such <b>annexes</b> must always be filed)</p> <p>unless replaced by the <b>amendments</b> enclosed.</p> <p><i>Where necessary, clarifications must be submitted on a separate sheet!</i></p> <p>If the EPO as International Preliminary Examining Authority has received <b>test reports</b>, these may be used as the basis of proceedings before the EPO.</p>	<p><b>6. Pièces destinées à la procédure devant l'OEB</b></p> <p><b>6.1</b> La procédure devant l'OEB agissant en qualité d'<b>office désigné (PCT I)</b> doit se fonder sur les pièces suivantes :</p> <p>les <b>pièces de la demande publiée</b> par le Bureau international (avec <b>toutes</b> les revendications, la description et les dessins), éventuellement avec les revendications modifiées conformément à l'article 19 du PCT</p> <p>dans la mesure où elles ne sont pas remplacées par les <b>modifications</b> jointes.</p> <p><i>Le cas échéant, des explications doivent être jointes sur une feuille additionnelle!</i></p> <p><b>6.2</b> La procédure devant l'OEB agissant en qualité d'<b>office élu (PCT II)</b> doit se fonder sur les pièces suivantes :</p> <p>les <b>pièces sur lesquelles se fonde le rapport d'examen préliminaire international</b>, y compris ses <b>annexes</b> éventuelles (De telles annexes sont toujours à joindre)</p> <p>dans la mesure où elles ne sont pas remplacées par les <b>modifications</b> jointes.</p> <p><i>Le cas échéant, des explications doivent être jointes sur une feuille additionnelle!</i></p> <p>Si l'OEB, agissant en qualité d'administration chargée de l'examen préliminaire international, a reçu des <b>rapports d'essais</b>, ceux-ci peuvent constituer la base de la procédure devant l'OEB.</p>


<p><b>7. Übersetzungen</b> Beigefügt sind die nachfolgend angekreuzten Übersetzungen in einer der Amtssprachen des EPA (Deutsch, Englisch, Französisch):</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Im Verfahren vor dem EPA als Bestimmungsort oder ausgewähltem Amt (PCT I + II):</li> <li><input type="checkbox"/> Übersetzung der ursprünglich eingereichten internationalen Anmeldung (Beschreibung, Ansprüche, etwaige Textbestandteile in den Zeichnungen), der veröffentlichten Zusammenfassung, und etwaiger Angaben über biologisches Material nach Regel 13<sup>ter</sup>.3 und 13<sup>ter</sup>.4 PCT</li> <li><input type="checkbox"/> Übersetzung der prioritätsbegründenden Anmeldung(en)</li> <li><input type="checkbox"/> Es wird hiermit erklärt, daß die internationale Anmeldung in ihrer ursprünglich eingereichten Fassung eine vollständige Übersetzung der früheren Anmeldung ist (Regel 38(5) EPU)</li> <li><input type="checkbox"/> Zusätzlich im Verfahren vor dem EPA als Bestimmungsort (PCT I):</li> <li><input type="checkbox"/> Übersetzung der nach Art. 19 PCT geänderten Ansprüche nebst Erklärung, falls diesem Verfahren vor dem EPA zugrunde gelegt werden sollen (siehe Feld 6)</li> <li><input type="checkbox"/> Zusätzlich im Verfahren vor dem EPA als ausgewähltem Amt (PCT II):</li> <li><input type="checkbox"/> Übersetzung der Anlagen zum internationalen vorläufigen Prüfungsbericht</li> </ul>	<p><b>7. Translations</b> Translations in one of the official languages of the EPO (English, French, German) are enclosed as crossed below:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> In proceedings before the EPO as designated or elected Office (PCT I + II):</li> <li>Translation of the international application (description, claims, any text in the drawings) as originally filed, of the abstract as published and of any indication under Rule 13<sup>ter</sup>.3 and 13<sup>ter</sup>.4 PCT regarding biological material</li> <li>Translation of the priority application(s)</li> <li>It is hereby declared that the international application as originally filed is a complete translation of the previous application (Rule 38(5) EPC)</li> <li><input type="checkbox"/> In addition, in proceedings before the EPO as designated Office (PCT I):</li> <li>Translation of amended claims and any statement under Art. 19 PCT, if the claims as amended are to form the basis for the proceedings before the EPO (see Section 6)</li> <li><input type="checkbox"/> In addition, in proceedings before the EPO as elected Office (PCT II):</li> <li>Translation of any annexes to the international preliminary examination report</li> </ul>	<p><b>7. Traductions</b> Vous trouverez ci-joint, les traductions cochées ci-après dans l'une des langues officielles de l'OEB (allemand, anglais, français) :</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Dans la procédure devant l'OEB agissant en qualité d'office désigné ou élu (PCT I + II):</li> <li>Traduction de la demande internationale telle que déposée initialement (description, revendications, textes figurant éventuellement dans les dessins), de l'abrégé publié, et de toutes indications visées aux règles 13<sup>ter</sup>.3 et 13<sup>ter</sup>.4 du PCT concernant le matériel biologique</li> <li>Traduction de la (des) demande(s) ouvrant le droit de priorité</li> <li>Il est déclaré par la présente que la demande internationale telle que déposée initialement est une traduction intégrale de la demande antérieure (règle 38(5) CBE)</li> <li><input type="checkbox"/> De plus, dans la procédure devant l'OEB agissant en qualité d'office désigné (PCT I):</li> <li>Traduction des revendications modifiées et de la déclaration faite conformément à l'article 19 du PCT, si la procédure devant l'OEB doit être fondée sur les revendications modifiées (voir la rubrique 6)</li> <li><input type="checkbox"/> De plus, dans la procédure devant l'OEB agissant en qualité d'office élu (PCT II):</li> <li>Traduction des annexes du rapport d'examen préliminaire international</li> </ul>
<p><input type="checkbox"/> <b>8. Biologisches Material</b> Die Erfindung bezieht sich auf bzw. verwendet biologisches Material, das nach Regel 28 EPU hinterlegt worden ist.</p> <p><input type="checkbox"/> Die Angaben nach Regel 28(1)c) EPU (falls noch nicht bekannt, die Hinterlegungsstelle und das (die) Bezugszeichen (Nummer, Symbole usw.) des Hinterlegers) sind in der internationalen Veröffentlichung oder in der gemäß Feld 7 eingereichten Übersetzung enthalten auf:</p> <p>Seite(n) / Zeile(n)</p> <p><input type="checkbox"/> Die Empfangsbescheinigung(en) der Hinterlegungsstelle</p> <p><input type="checkbox"/> ist (sind) beigefügt</p> <p><input type="checkbox"/> wird (werden) nachgereicht</p> <p><input type="checkbox"/> Verzicht auf die Verpflichtung des Antragstellers nach Regel 28(3) EPU auf gesondertem Schriftstück</p>	<p><input type="checkbox"/> <b>8. Biological material</b> The invention relates to and/or uses biological material deposited under Rule 28 EPC.</p> <p><input type="checkbox"/> The particulars referred to in Rule 28(1)(c) EPC (if not yet known, the depository institution and the identification reference(s) [number, symbols etc.] of the depositor) are given in the international publication or in the translation submitted under Section 7 on:</p> <p>page(s) / line(s)</p> <p><input type="checkbox"/> The receipt(s) of deposit issued by the depository institution</p> <p><input type="checkbox"/> is (are) enclosed</p> <p><input type="checkbox"/> will be filed at a later date</p> <p><input type="checkbox"/> Waiver of the right to an undertaking from the requester pursuant to Rule 28(3) EPC attached.</p>	<p><input type="checkbox"/> <b>8. Matière biologique</b> L'invention concerne et/ou utilise de la matière biologique, déposée conformément à la règle 28 CBE.</p> <p><input type="checkbox"/> Les indications visées à la règle 28(1)c) CBE (si non encore connues, l'autorité de dépôt et la (les) référence(s) d'identification [numéro ou symboles etc.] du déposant) figurent dans la publication internationale ou dans une traduction produite conformément à la rubrique 7 à la / aux:</p> <p>page(s) / ligne(s)</p> <p><input type="checkbox"/> Le(s) récépissé(s) de dépôt délivré(s) par l'autorité de dépôt</p> <p><input type="checkbox"/> est (sont) joint(s)</p> <p><input type="checkbox"/> sera (seront) produit(s) ultérieurement</p> <p><input type="checkbox"/> Renonciation, sur document distinct, à l'engagement du requérant au titre de la règle 28(3) CBE.</p>



<p><b>9. Nucleotid- und Aminosäuresequenzen</b> Die nach Regeln 5.2 und 13<sup>ter</sup> PCT sowie Regel 111(3) EPÜ erforderlichen Unterlagen liegen dem EPA bereits vor.</p> <p><input type="checkbox"/> Das schriftliche Sequenzprotokoll wird anliegend nachgereicht.</p> <p><input type="checkbox"/> Das Sequenzprotokoll geht nicht über den Inhalt der Anmeldung in der ursprünglich eingereichten Fassung hinaus.</p> <p><input type="checkbox"/> Der vorgeschriebene Datenträger ist beigelegt.</p> <p><input type="checkbox"/> Die auf dem Datenträger gespeicherte Information stimmt mit dem schriftlichen Sequenzprotokoll überein.</p>	<p><b>9. Nucleotide and amino acid sequences</b> The items necessary in accordance with Rules 5.2 and 13<sup>ter</sup> PCT and Rule 111(3) EPC have already been furnished to the EPO.</p> <p>The written sequence listing is furnished herewith.</p> <p>The sequence listing does not include matter which goes beyond the content of the application as filed.</p> <p>The prescribed data carrier is enclosed.</p> <p>The information recorded on the data carrier is identical to the written sequence listing.</p>	<p><b>9. Séquences de nucléotides et d'acides aminés</b> Les pièces requises selon les règles 5.2 et 13<sup>ter</sup> PCT et la règle 111(3) CBE ont déjà été déposées auprès de l'OEB.</p> <p>La liste de séquences écrite est produite ci-joint.</p> <p>La liste de séquences ne contient pas d'éléments s'étendant au-delà du contenu de la demande telle qu'elle a été déposée.</p> <p>Le support de données prescrit est joint.</p> <p>L'information figurant sur le support de données est identique à celle que contient la liste de séquences écrites.</p>
<p><b>10. Benennungsgebühren</b></p> <p><input checked="" type="checkbox"/> 10.1 Es ist derzeit beabsichtigt, den siebenfachen Betrag einer Benennungsgebühr zu entrichten. Damit gelten die Benennungsgebühren für alle Vertragsstaaten des EPÜ<sup>1</sup> als entrichtet (Art. 2 Nr. 3 GebO), soweit sie in der Internationalen Anmeldung bestimmt sind<sup>2</sup>.</p> <p><input type="checkbox"/> 10.2 Abweichend von der Erklärung in Nr. 10.1 ist derzeit beabsichtigt, weniger als sieben Benennungsgebühren für folgende in der Internationalen Anmeldung bestimmte Vertragsstaaten des EPÜ<sup>1</sup> zu entrichten:</p> <p>(1) <input type="text"/> _____</p> <p>(2) <input type="text"/> _____</p> <p>(3) <input type="text"/> _____</p> <p>Soweit unter Nr. 10.2 Vertragsstaaten aufgeführt sind, wird beantrag, für die dort nicht aufgeführten Vertragsstaaten von der Zustellung einer Mitteilung nach Regel 108(3) EPÜ abzusehen.</p> <p><input checked="" type="checkbox"/> 10.3 Wird ein automatischer Abbuchungsauftrag erteilt (Feld 12), so wird das EPA beauftrag, bei Ablauf der Grundfrist nach Regel 107 (1)d) EPÜ den siebenfachen Betrag einer Benennungsgebühr abzubuchen. Ist eine Erklärung nach Nr. 10.2 abgegeben worden, so sollen die Benennungsgebühren nur für die dort angegebenen Vertragsstaaten abgebucht werden, sofern dem EPA nicht bis zum Ablauf der Grundfrist ein anderslautender Auftrag zugeht.</p>	<p><b>10. Designation fees</b></p> <p>10.1 It is currently intended to pay seven times the amount of the designation fee. The designation fees for all the EPC contracting states<sup>1</sup> designated in the international application<sup>2</sup> are thereby deemed to have been paid (Art. 2 No. 3 RFees).</p> <p>10.2 The declaration in No. 10.1 does not apply. Instead, it is currently intended to pay fewer than seven designation fees for the following EPC contracting states<sup>1</sup> designated in the international application:</p> <p>(4) <input type="text"/> _____</p> <p>(5) <input type="text"/> _____</p> <p>(6) <input type="text"/> _____</p> <p>If contracting states are indicated under No. 10.2, it is requested that no communication under Rule 108(3) EPC be issued for contracting states not thus indicated.</p> <p>10.3 If an automatic debit order has been issued (Section 12), the EPO is authorised, on expiry of the basic period under Rule 107(1)(d) EPC, to debit seven times the amount of the designation fee. If states are indicated under No. 10.2, the EPO will debit designation fees only for those states, unless instructed otherwise before the basic period expires.</p>	<p><b>10. Taxes de désignation</b></p> <p>10.1 Il est actuellement envisagé de payer un montant correspondant à sept fois la taxe de désignation. Les taxes de désignation sont ainsi réputées payées pour tous les Etats contractants de la CBE<sup>1</sup> désignés dans la demande internationale<sup>2</sup> (art. 2, point 3 du RRT).</p> <p>10.2 Contrairement à ce qui est indiqué au n° 10.1, il est actuellement envisagé de payer moins de sept taxes de désignation pour les Etats contractants de la CBE<sup>1</sup> suivants désignés dans la demande internationale :</p> <p>(4) <input type="text"/> _____</p> <p>(5) <input type="text"/> _____</p> <p>(6) <input type="text"/> _____</p> <p>Si des Etats contractants sont mentionnés au n° 10.2, prière de ne pas procéder à la signification d'une notification prévue par la règle 108(3) CBE pour les Etats contractants n'y étant pas mentionnés.</p> <p>10.3 Si un ordre de prélèvement automatique est donné (rubrique 12), il est demandé à l'OEB de prélever, à l'expiration du délai normal visé à la règle 107(1)d) CBE, un montant correspondant à sept fois la taxe de désignation. Si une déclaration a été faite au n° 10.2, les taxes de désignation ne sont à prélever que pour les Etats contractants qui y sont indiqués, sauf instruction contraire reçue par l'OEB avant l'expiration du délai normal.</p>

<sup>1</sup> Stand bei Drucklegung: 27 Vertragsstaaten, und zwar: / Status when this form was printed: 27 contracting states, namely / Situation à la date d'impression: 27 Etats contractants, à savoir: AT Österreich / Austria / Autriche, BE Belgien / Belgium / Belgique, BG Bulgarien / Bulgaria / Bulgarie, CH / LI Schweiz und Liechtenstein / Switzerland and Liechtenstein / Suisse et Liechtenstein, CY Zypern / Cyprus / Chypre, CZ Tschechische Republik / Czech Republic / République tchèque, DE Deutschland / Germany / Allemagne, DK Dänemark / Denmark / Danemark, EE Estland / Estonia / Estonie, ES Spanien / Spain / Espagne, FI Finnland / Finland / Finlande, FR Frankreich / France / France, GB Vereinigtes Königreich / United Kingdom / Royaume-Uni, GR Griechenland / Greece / Grèce, HU Ungarn / Hungary / Hongrie, IE Irland / Ireland / Irlande, IT Italien / Italy / Italie, LU Luxemburg / Luxembourg / Luxembourg, MC Monaco / Monaco / Monaco, NL Niederlande / Netherlands / Pays-Bas, PT Portugal / Portugal / Portugal, RO Rumänien / Romania / Roumanie, SE Schweden / Sweden / Suède, SI Slowenien / Slovenia / Slovénie, SK Slowakische Republik / Slovak Republic / République slovaque, TR Türkei / Turkey / Turquie

<sup>2</sup> Für folgende Staaten nur möglich, falls in der Internationalen Anmeldung am oder nach folgendem Tag bestimmt: Slowakische Republik, Bulgarien, Tschechische Republik und Estland: 1. Juli 2002, Slowenien: 1. Dezember 2002, Ungarn: 1. Januar 2003 und Rumänien: 1. März 2003. / For the following states this is possible only if they are designated in the international application on or after the stated date: Slovak Republic, Bulgaria, Czech Republic and Estonia: 1 July 2002, Slovenia: 1 December 2002, Hungary: 1 January 2003 and Romania: 1 March 2003. / En ce qui concerne les Etats suivants seulement si la désignation a été effectuée dans la demande internationale à la date suivante ou à une date ultérieure: République slovaque, Bulgarie, République tchèque et Estonie: 1<sup>er</sup> juillet 2002, Slovénie: 1<sup>er</sup> décembre 2002, Hongrie: 1<sup>er</sup> janvier 2003 et Roumanie: 1<sup>er</sup> mars 2003.

<p><input checked="" type="checkbox"/> 11. <b>Erstreckung des europäischen Patents</b> Bei Zahlung der Erstreckungsgebühr(en) gilt diese Anmeldung auch als wirksamer Erstreckungsantrag für die in der internationalen Anmeldung bestimmten »Erstreckungsstaaten«. Es ist beabsichtigt, diese Gebühren für folgende Staaten zu entrichten:</p> <p><input checked="" type="checkbox"/> <b>YU</b></p> <p><input type="checkbox"/> SI Slowenien<sup>1)</sup></p> <p><input type="checkbox"/> LT Litauen</p> <p><input checked="" type="checkbox"/> LV Lettland</p> <p><input checked="" type="checkbox"/> AL Albanien</p> <p><input type="checkbox"/> RO Rumänien<sup>1)</sup></p> <p><input checked="" type="checkbox"/> MK Ehemalige jugoslawische Republik Mazedonien</p> <p><input checked="" type="checkbox"/> BA</p> <p><input checked="" type="checkbox"/> <b>HR</b></p> <p>1) Für Slowenien und Rumänien nur möglich, falls in der internationalen Anmeldung bis 30. November 2002 (Slowenien) oder bis 28. Februar 2003 (Rumänien) bestimmt. / For Slovenia and Romania this is possible only if they are designated in the international application up to 30 November 2002 (Slovenia) or 28 February 2003 (Romania). / En ce qui concerne la Slovénie et la Roumanie, seulement si la désignation a été effectuée dans la demande internationale jusqu'au 30 novembre 2002 (Slovénie) ou jusqu'au 28 février 2003 (Roumanie).</p> <p>2) Platz für Staaten, mit denen »Erstreckungsabkommen« nach Drucklegung dieses Formblatts in Kraft treten und die in der internationalen Anmeldung bestimmt waren. / Space for States with which »extension agreements« enter into force after this form has been printed and which were designated in the international application. / Prévu pour des Etats à l'égard desquels des »accords d'extension« entreront en vigueur après l'impression du présent formulaire et qui ont été désignés dans la demande internationale.</p>	<p>11. <b>Extension of the European patent</b> On payment of the extension fee(s) this application is also deemed to be a request for extension to all the »extension states« designated in the international application. It is intended to pay the fee(s) for the following states:</p> <p><b>Serbia and Montenegro</b></p> <p>Slovenia<sup>1)</sup></p> <p>Lithuania</p> <p>Latvia</p> <p>Albania</p> <p>Romania<sup>1)</sup></p> <p>Former Yugoslav Republic of Macedonia</p> <p>Bosnia and Herzegovina<sup>2)</sup></p> <p><b>Croatia</b></p>	<p>11. <b>Extension des effets du brevet européen</b> La taxe (Les taxes) d'extension payée(s), la présente demande est également réputée être une demande d'extension à tous les »Etats autorisant l'extension« désignés dans la demande internationale. Il est envisagé de payer la taxe (les taxes) d'extension pour les Etats suivants:</p> <p>Slovénie<sup>1)</sup></p> <p>Lituanie</p> <p>Lettonie</p> <p>Albanie</p> <p>Roumanie<sup>1)</sup></p> <p>Ex-République yougoslave de Macédoine<sup>2)</sup></p>
<p>12. <b>Automatischer Abbuchungsauftrag (Nur möglich für Inhaber von beim EPA geführten laufenden Konten)</b></p> <p><input type="checkbox"/> Das EPA wird beauftragt, nach Maßgabe der Vorschriften über das automatische Abbuchungsverfahren fällige Gebühren und Auslagen vom untenstehenden laufenden Konto abzubuchen. In Bezug auf die Benennungsgebühren wird auf Feld 10.3 verwiesen. Das EPA wird ferner beauftragt, die Erstreckungsgebühren für jeden in Feld 11 angekreuzten »Erstreckungsstaat« bei Ablauf der Grundfrist zu ihrer Zahlung abzubuchen, sofern ihm nicht bis dahin ein anderslautender Auftrag zugeht.</p> <p>Nummer und Kontoinhaber</p>	<p>12. <b>Automatic debit order (for EPO deposit account holders only)</b></p> <p>The EPO is hereby authorised, under the Arrangements for the automatic debiting procedure, to debit from the deposit account below any fees and costs falling due. For designation fees, see Section 10.3. The EPO is also authorised, on expiry of the basic period for paying the extension fees, to debit those fees for each of the »extension states« marked with a cross in Section 11, unless instructed otherwise before the said period expires.</p> <p>Number and account holder</p>	<p>12. <b>Ordre de prélèvement automatique (uniquement possible pour les titulaires de comptes courants ouverts auprès de l'OEB)</b></p> <p>Par la présente, il est demandé à l'OEB de prélever du compte courant ci-dessous les taxes et frais venant à échéance, conformément à la réglementation relative au prélèvement automatique. Pour les taxes de désignation, se reporter à la rubrique 10.3. Il est en outre demandé à l'OEB de prélever, à l'expiration du délai normal prévu pour leur paiement, les taxes d'extension pour chaque »Etat autorisant l'extension« coché à la rubrique 11, sauf instruction contraire reçue avant l'expiration de ce délai.</p> <p>Numéro et titulaire du compte</p>
<p><input type="checkbox"/> 13. <b>Eventuelle Rückzahlungen auf das beim EPA geführte laufende Konto</b></p> <p>Nummer und Kontoinhaber</p>	<p>13. <b>Any reimbursement to EPO deposit account</b></p> <p>Number and account holder</p> <p>28070103</p>	<p>13. <b>Remboursements éventuels à effectuer sur le compte courant ouvert auprès de l'OEB</b></p> <p>Numéro et titulaire du compte</p>
<p>14. <b>Unterschrift(en) des (der) Anmelders(s) oder Vertreters</b></p> <p>Ort / Datum</p> <p>Für Angestellte (Art. 133(3) EPÜ) mit allgemeiner Vollmacht:</p> <p>Nr.</p> <p>Name(n) des (der) Unterzeichneten bitte in Druckschrift wiederholen. Bei juristischen Personen bitte auch die Stellung des (der) Unterzeichneten innerhalb der Gesellschaft in Druckschrift angeben.</p>	<p>14. <b>Signature(s) of applicant(s) or representative</b></p> <p>Rinaldo FERRECCIO</p> <p></p> <p>Place / Date Milano, August 10, 2006</p> <p>For employees (Art. 133(3) EPC) having a general authorisation:</p> <p>No.</p> <p>Please print name(s) under signature(s). In the case of legal persons, the position of the signatory within the company should also be printed.</p>	<p>14. <b>Signature(s) du (des) demandeur(s) ou du mandataire</b></p> <p>Lieu / Date</p> <p>Pour les employés (art. 133(3) CBE) disposant d'un pouvoir général:</p> <p>N°</p> <p>Le ou les noms des signataires doivent être indiqués en caractères d'imprimerie. S'il s'agit d'une personne morale, la position occupée au sein de celle-ci par le ou les signataires doit également être indiquée en caractères d'imprimerie.</p>

# CLAIMS

1. A composition comprising CoQ10 and a pharmaceutically acceptable carrier.
2. The composition of claim 1, wherein the composition comprises:  
5 Coenzyme Q10, phospholipon 90, glycerol, butylated hydroxytoluene (BHT), ethanol, medium chain triglycerides (MCT) and lavender.
3. The composition of claim 2, wherein the phospholipon 90 is phospholipon 90G.
4. The composition of claim 2, wherein the phospholipon 90 is  
10 phospholipon 90H.
5. The composition of claim 2, wherein the composition further comprises phospholipon 90G and phospholipon 90H.
6. The composition of claim 1, wherein the composition comprises between about 1% to about 25% (w/w) of Coenzyme Q10.
- 15 7. The composition of claim 1, wherein the composition comprises between about 1% to about 20% (w/w) of Coenzyme Q10.
8. Use of a composition comprising Coenzyme Q10 in the manufacture of a medicament for the treatment of cancer.
9. Use according to claim 8, wherein said medicament contains a  
20 therapeutically effective amount of Coenzyme Q10 and is administered to a patient in need thereof, so as to contact a tumor cell with the composition, which results in the lysis of the tumor cell, thereby treating the cancer patient.
10. Use according to claim 8, wherein said medicament is  
25 administered to a patient in need thereof, in order to inhibit tumor cell growth.
11. Use according to claim 8, wherein said medicament is

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administered to a patient in need thereof, in order to induce apoptosis in tumor cells.

12. Use according to claim 8, wherein said medicament is administered to a patient in need thereof, in order to inhibit  
5 angiogenesis in a tumor, by contacting the tumor with the composition.

13. Use according to any one of claims 8 to 12, wherein the composition comprises about 1% up to 25% w/w of Coenzyme Q10.

14. Use according to any one of claims 8 to 13, wherein the composition comprises about 1% to about 20% w/w of Coenzyme Q10.

10 15. Use according to claim 8 or 9, wherein the composition comprising the Coenzyme Q10 is formulated as a topical cream.

16. Use according to any one of claims 8 and 9, wherein a therapeutic effective amount of the Coenzyme Q10-composition is administered with one or more chemotherapeutic agents.

15 17. Use according to claim 16, wherein the chemotherapeutic agent can be co-administered, precede, or administered after the composition comprising a therapeutic effective amount of Coenzyme Q10.

18. Use according to claim 16 or 17, wherein the chemotherapeutic agent is selected from the group consisting of cyclophosphamide (CTX,  
20 25 mg/kg/day, *p.o.*), taxanes (paclitaxel or docetaxel), busulfan, cisplatin, cyclophosphamide, methotrexate, daunorubicin, doxorubicin, melphalan, cladribine, vincristine, vinblastine, and chlorambucil.

19. Use according to any one of claims 8 or 9, wherein treatment results in inhibition of tumor cell growth.

25 20. Use according to claim 11, wherein the medicament induces apoptosis in at least about 30% of tumor cells as measured by mitochondrial membrane dye assay and or Annexin-VPE assay.

21. Use according to claim 11, wherein the medicament induces apoptosis in at least about 50% of tumor cells as measured by

mitochondrial membrane dye assay and or Annexin-VPE assay.

22. Use according to claim 11, wherein the medicament induces apoptosis in at least about 60% of tumor cells as measured by mitochondrial membrane dye assay and or Annexin-VPE assay.

5 23. Use according to claim 11, wherein the medicament induces apoptosis in at least about 75% of tumor cells as measured by mitochondrial membrane dye assay and or Annexin-VPE assay.

24. Use according to claim 11, wherein the medicament induces apoptosis in at least about 90% of tumor cells as measured by  
10 mitochondrial membrane dye assay and or Annexin-VPE assay.

25. Use according to claim 11, wherein the medicament induces apoptosis in at least about 99.9% of tumor cells as measured by mitochondrial membrane dye assay and or Annexin-VPE assay.

26. A kit comprising:

15 coenzyme Q10,

phospholipon 90,

glycerol,

butylated hydroxytoluene (BHT),

ethanol,

20 medium chain triglycerides (MCT), and

lavender.

27. The kit of claim 26, wherein the phospholipon 90 is phospholipon 90G.

28. The kit of claim 26, wherein the phospholipon 90 is phospholipon  
25 90H.

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29. The kit of claim 26, wherein the phospholipon 90 is phospholipon 90G and phospholipon 90H.

30. The kit of claim 26, wherein the Coenzyme Q10 is provided between about 1% to about 30% (w/w).



P.B.5818 - Patentlaan 2  
2280 HV Rijswijk (ZH)  
☎ (070) 3 40 20 40  
FAX (070) 3 40 30 16

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NELSON, Gregory, A.  
Akerman Senterfitt  
Customer No. 30448  
P.O. Box 3188  
West Palm Beach, FL 33402-3188  
ETATS-UNIS D'AMERIQUE



EPO Customer Services

Tel.: +31 (0)70 340 45 00

Date

08.06.06

Reference	Application No./Patent No. 05711599.0 - PCT/US2005001581
Applicant/Proprietor University of Miami	

### Entry into the European phase before the European Patent Office

These notes describe the procedural steps required for entry into the European phase before the European Patent Office (EPO). You are advised to read them carefully: failure to take the necessary action in time can lead to your application being deemed withdrawn.

1. The above-mentioned international patent application has been given European application No. **05711599.0**.
2. Applicants **without** a residence or their principal place of business in an EPC contracting state may themselves initiate European processing of their international applications, provided they do so before expiry of the 31st month from the priority date (see also point 6 below).

**During the European phase before the EPO as designated or elected Office, however, such applicants must be represented by a professional representative (Arts. 133(2) and 134(1), (7) EPC).**

Procedural acts performed after expiry of the 31st month by a professional representative who acted during the international phase but is not authorised to act before the EPO have no legal effect and therefore lead to loss of rights.

**Please note that a professional representative authorised to act before the EPO and who acted for the applicant during the international phase does not automatically become the representative for the European phase. Applicants are therefore strongly advised to appoint in good time any representative they wish to initiate the European phase for them; otherwise, the EPO has to send all communications direct to the applicant.**

3. Applicants **with** a residence or their principal place of business in an EPC contracting state are not obliged to appoint, for the European phase before the EPO as designated or elected Office, a professional representative authorised to act before the EPO.  
**However, in view of the complexity of the procedure it is recommended that they do so.**
4. Applicants and professional representatives are also strongly advised to initiate the European phase using EPO Form 1200 (available free of charge from the EPO). This however is not compulsory.



5. **To enter the European phase before the EPO, the following acts must be performed.**  
(N.B.: Failure validly to do so will entail loss of rights or other adverse legal consequences.)

5.1 If the EPO is acting as **designated or elected Office** (Arts. 22(1)(3) and 39(1) PCT-respectively), applicants must, within 31 months from the date of filing or (where applicable) the earliest priority date:

a) Supply a translation of the international application into an EPO official language, if the International Bureau did not publish the application in such a language (Art. 22(1) PCT and R. 107(1)(a) EPC).

**If the translation is not filed in time, the international application is deemed withdrawn before the EPO (R. 108(1) EPC).**

This loss of rights is deemed not to have occurred if the translation is then filed within a two-month grace period as from notification of an EPO communication, provided a surcharge is paid at the same time (R. 108(3) EPC).

b) Pay the national basic fee (EUR 170,00) and, where a supplementary European search report has to be drawn up, the search fee (EUR 720,00 ; R. 107(1)(c) and (e) EPC).

c) If the time limit under Article 79(2) EPC expires before the 31-month time limit, pay the designation fee (EUR 80,00) for each contracting state designated (R. 107(1)(d) EPC).

d) If the time limit under Article 94(2) EPC expires before the 31-month time limit, file the written request for examination and pay the examination fee (EUR 1490,00 ; R. 107(1)(f) EPC).

e) Pay the third-year renewal fee (EUR 400,00) if it falls due before expiry of the 31-month time limit (R. 107(1)(g) EPC).

If the fees under (b) to (d) above are not paid in time, or the written request for examination is not filed in time, the international application is deemed withdrawn before the EPO, or the contracting-state designation(s) in question is (are) deemed withdrawn (R. 108(1) and (2) EPC). However, the fees may still be validly paid within a two-month grace period as from notification of an EPO communication, provided the necessary surcharges are paid at the same time (R. 108(3) EPC). For the renewal fee under (e) above, the grace period is six months from the fee's due date (Art. 86(2) EPC).

For an overview of search and examination fees, see OJ EPO 11/2005, 577 and 03/2006.

5.2 If the application documents on which the European grant procedure is to be based comprise more than ten claims, a claims fee is payable within the 31-month time limit under Rule 107(1) EPC for the eleventh and each subsequent claim (R. 110(1) EPC). The fee can however still be paid within a one-month grace period as from notification of an EPO communication pointing out the failure to pay (R. 110(2) EPC).

6. If the applicant had a representative during the application's international phase, the present notes will be sent to the representative, asking him to inform the applicant accordingly.

**All subsequent communications will be sent to the applicant, or - if the EPO is informed of his appointment in time - to the applicant's European representative.**





7. For more details about time limits and procedural acts before the EPO as designated and elected Office, see the EPO brochure

How to get a European patent  
Guide for applicants - Part 2  
PCT procedure before the EPO - "Euro-PCT"

This brochure, the list of professional representatives before the EPO, Form 1200 and details of the latest fees are now all available on the Internet under

<http://www.european-patent-office.org>

Receiving section



From the INTERNATIONAL BUREAU

**PCT**

## NOTIFICATION OF ELECTION

(PCT Article 31(7) and Rule 61.2)

To:

European Patent Office  
Phoenix Support Help Desk  
Att. C. Hamm, Room S00G12, P.O. Box 5818  
NL- 2280 HV Rijswijk  
PAYS-BAS

in its capacity as elected Office

Date of mailing ( <i>day/month/year</i> ) 09 February 2006 (09.02.2006)	Applicant's or agent's file reference 7230-21WO
International application No. PCT/US2005/001581	Priority date ( <i>day/month/year</i> ) 22 January 2004 (22.01.2004)
International filing date ( <i>day/month/year</i> ) 21 January 2005 (21.01.2005)	
Applicant UNIVERSITY OF MIAMI et al	

1. The designated Office is hereby notified of its election made in the demand filed with the International Preliminary Examining Authority on:

22 September 2005 (22.09.2005)

2. The election ☐ was  
☒ was not

made before the expiration of 19 months from the priority date (PCT Article 39(1)(a)).

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Facsimile No.+41 22 740 14 35

Authorized officer

Agnes Wittmann-Regis

Facsimile No.+41 22 338 89 70